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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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7590 07/14/2003

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EXAMINER

KRISHNAN, GANAPATHY

ART UNIT PAPER NUMBER

1623

DATE MAILED: 07/14/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/909,797

Applicant(s)

DIAZ ET AL.

Examiner

Ganapathy Krishnan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,5-16 and 18-46 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-3,5-16, and 18-46 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ 6) ☐ Other:

DETAILED ACTION

Amendment B filed June 11, 2003 has been received and carefully considered. The following information provided in the amendment affects the instant application:

1. Claims 4, 17 and 47-55 have been cancelled.
2. Claims 1 and 2 have been amended to incorporate the limitations of claim 4.
3. Claims 3 and 26 have been amended to correct spelling errors.
4. Remarks drawn to the amendments and rejections.

Claims 1-3, 5-16 and 18-46 are pending.

The finality of the previous office action (March 11, 2003) is withdrawn. An action on the merits of the pending claims is contained herein below.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 10-16, 18-37 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for preparing one alkali or alkaline-earth metal salt of one sulfated polysaccharide of heparin, does not reasonably provide enablement for preparing more than two alkali or alkaline-earth salt of more than two sulfated polysaccharide of heparin and treatment of thrombotic accidents. The specification does not enable any person

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skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

A conclusion of lack of enablement means that, based on the evidence regarding each of the factors below, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation.

- (A) The breadth of the claims
- (B) The state of the prior art
- (C) The level of predictability in the art
- (D) The amount of direction provided by the inventor
- (E) The existence of working examples
- (F) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

The breadth of the claims

Claims 10-16 and 18-37 are drawn to method of preparing at least one alkali or alkaline-earth metal salt of at least one sulfated polysaccharide of heparin and a method of treating arterial thrombotic accidents. The scope of the claims is seen to include the method of preparing two or more alkali or alkaline earth metal salts of two or more sulfated polysaccharide of heparin and administration of the said compounds for the treatment of thrombotic accidents.

The state of the prior art

The examiner notes that prior art mentions methods for making a single alkali or alkaline-earth metal salt of one sulfated polysaccharide of heparin. However, there is no

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disclosure of methods of preparing two or more alkali or alkaline earth metal salts of two or more sulfated polysaccharide of heparin and administration of the said compounds for the treatment of thrombotic accidents seen in the prior art. The prior art appears to be silent with regard to the said methods and procedures recognized by skilled artisans in the field.

The level of predictability in the art

The examiner acknowledges the probability that the method of preparing two or more alkali or alkaline earth metal salts of two or more sulfated polysaccharide of heparin and the administration of the said compounds would have a reasonable expectation of success for treating thrombotic accidents. There is not seen sufficient data to substantiate that two or more alkali or alkaline earth metal salts of two or more sulfated polysaccharide of heparin could be made and the administration of the said compounds would have a reasonable expectation of success for treating thrombotic accidents as instantly claimed.

The amount of direction provided by the inventor

The instant specification is not seen to provide enough guidance that would allow a skilled artisan to extrapolate from the disclosure and the examples provided to prepare two or more alkali or alkaline earth metal salts of two or more sulfated polysaccharide of heparin and the administration of the said compounds for treating thrombotic accidents. The specification also fails to direct the skilled artisan in correlative prior art procedures which might provide the basis for the same.

The existence of working examples

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The working examples set forth in the instant specification are drawn to method of making a single alkali or alkaline-earth metal salt of one sulfated polysaccharide of heparin and their anti-Xa and anti-IIa activity. The skilled artisan in this field would not extrapolate the instant method to prepare two or more alkali or alkaline earth metal salts of two or more sulfated polysaccharide of heparin or the use of the same for treating thrombotic accidents from the examples provided.

The quantity of experimentation needed to make or use the invention based on the content of the disclosure

Indeed, in view of the information set forth, the instant disclosure is not seen to be sufficient to enable the preparation of two or more alkali or alkaline earth metal salts of two or more sulfated polysaccharide of heparin and the administration of the said compounds for treating thrombotic accidents as set forth in the instant specifications.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 39, 40, 42, 43, 45 and 46 were indicated as allowable. This is withdrawn for reasons given below.

Claims 39-46 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claims 39, 40, 42, 43, 45 and 46 drawn to therapeutic methods incorporate processing steps of claims 10 and 26. The recitation in a dependent claim of "the source of an active agent" to be used in a method from which the said claim depends, wherein "the source of said active agent" does not result in a patentably distinguishable methodological and manipulative difference in how said active agent's source impacts the method from which it depends, renders the claims in which it occurs and which depend therefrom indefinite for failing to distinctly articulate how such a recitation further limits the method from which said dependent claims applicant regards as the invention.

The term "accidents" in claims 41-46 is a relative term which renders the claims indefinite. The term "accidents" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-3 and 5-9 are rejected under 35 U.S.C. 102(e) as being anticipated by
Mardiguian (US 6384021).

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Applicants have amended claims 1 and 2 to recite an antiXa activity of the instant composition in the range of from 125 to 150 IU/mg.

Mardiguian discloses a composition of heparin in the molecular weight range as instantly claimed that has an anti Xa activity between 100 and 150 IU/mg and an anti IIa activity of less than or equal to 10 IU/mg. (see col. 5, 20-44). The heparin composition has 10 to 12 saccharide units and the one end unit has a 4,5-unsaturated glucuronic acid 2-O-sulphate unit (col. 2, 22-26 and col. 5, see general formula). The examples given in the Table (col. 5, Analysis of the products) shows products with antiXa:antiIIa activity ratio of greater than 10:1 and some with a ratio of greater than 25. The composition is also shown to contain sodium (alkali metal) salt.

Claims 38, 41 and 44 are rejected under 35 U.S.C. 102(e) as being anticipated by Mardiguian (US 6384021).

Mardiguian also discloses that the compositions of his invention are useful in the prophylaxis and treatment of venous and arterial thrombosis (col. 2, lines 28-31 and col. 6, lines 35-44).

Conclusion

1. Claims 1-3, 5-16, 18-46 are rejected.

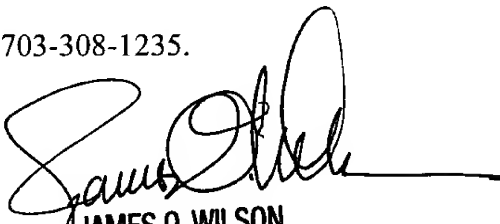
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ganapathy Krishnan whose telephone number is 703-305-4837. The examiner can normally be reached on 8.30am-5pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 703-308-4624. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

GK
July 14, 2003



JAMES O. WILSON
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600